

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effectiveness of compassion focus therapy with transdiagnostic treatment on symptoms of migraine , perceived stress ,dark personality and mental toughness in patients with migraine

#### Protocol summary

##### Study aim

Effectiveness and comparison of Compassion Focused Therapy and Transdiagnostic Treatment on migraine symptoms, perceived stress, dark personality and mental strength of patients with migraine

##### Design

At first, 45 migraine patients who were diagnosed with migraine by a neurologist were selected. They were randomly assigned to two experimental and one control groups.

##### Settings and conduct

This study was conducted at Shahin Shahr Oil Industry Clinic from October to December 2017. During this study, two experimental groups received psychological training and drug therapy, and the control group received only medication. Before the intervention, the pre-test was performed in three groups and after intervention, three groups of post-test were performed and after two months follow up.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of migraine by the neurologist, having at least 3rd grade education, satisfaction with the company's research, and the absence of any acute and psychological illness other than migraine, which leads to the use of medication.  
Non-inclusion criteria: receiving psychological treatment in the last 6 months.

##### Intervention groups

Intervention group 1: Compassion Focused Therapy with drug therapy  
Intervention group 2: Transdiagnostic Treatment with drug therapy  
Control group: only drug therapy

##### Main outcome variables

Ahvaz migraine headache questionnaire score; Chohen Perceived stress scale score; Dark Personality Inventory score; Mental Toughness Questionnaire score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180627040263N1**

Registration date: **2018-09-18, 1397/06/27**

Registration timing: **retrospective**

Last update: **2018-09-18, 1397/06/27**

Update count: **0**

##### Registration date

2018-09-18, 1397/06/27

##### Registrant information

##### Name

Mehdi Ashharian dokht

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 4525 4625

##### Email address

a.yarmohammadian@edu.ui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-09-23, 1396/07/01

##### Expected recruitment end date

2017-10-07, 1396/07/15

##### Actual recruitment start date

2017-09-29, 1396/07/07

##### Actual recruitment end date

2017-10-07, 1396/07/15

##### Trial completion date

2017-12-22, 1396/10/01

## Scientific title

Comparison of the effectiveness of compassion focus therapy with transdiagnostic treatment on symptoms of migraine , perceived stress ,dark personality and mental toughness in patients with migraine

## Public title

Comparison of the effectiveness of compassion focus therapy with transdiagnostic treatment on symptoms of migraine

## Purpose

Education/Guidance

## Inclusion/Exclusion criteria

### Inclusion criteria:

Diagnosis of migraines by a neurologist having at least 3rd grade education Wiling to participate in the research not having any acute and psychological illness other than migraine

### Exclusion criteria:

Psychological treatment in the last 6 months

## Age

From **20 years** old to **50 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **45**

Actual sample size reached: **45**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Accidental assignment to intervention and control groups which was done through simple randomization. Random numbers table was used to create random sequences. In order to hide the random allocation, non-transparent sealed envelopes were used.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee on Research, Shahrekord Branch, Islamic Azad University

##### Street address

Shahrekord Branch, Islamic Azad University,

Rahmateyeh Blvd

#### City

Shahrekord

#### Province

Chahar-Mahal-va-Bakhtiari

#### Postal code

8813733395

#### Approval date

2018-05-13, 1397/02/23

#### Ethics committee reference number

IR.IAU.SHK.REC.1397.002

## Health conditions studied

### 1

#### Description of health condition studied

Migraine

#### ICD-10 code

G43

#### ICD-10 code description

Migraine without aura [common migraine]

## Primary outcomes

### 1

#### Description

Ahvaz migraine headache questionnaire score

#### Timepoint

At the beginning of the study, after the end of the intervention and 2 months after the end of the intervention

#### Method of measurement

Ahvaz migraine headache questionnaire

### 2

#### Description

Chohen Perceived stress scale score

#### Timepoint

At the beginning of the study, after the end of the intervention and 2 months after the end of the intervention

#### Method of measurement

Chohen Perceived stress scale

### 3

#### Description

Dark Personality Inventory score

#### Timepoint

At the beginning of the study, after the end of the intervention and 2 months after the end of the intervention

#### Method of measurement

Johnson & Webster Darkness Personality Questionnaire

### 4

#### Description

Mental Toughness Questionnaire score

## Timepoint

At the beginning of the study, after the end of the intervention and 2 months after the end of the intervention

## Method of measurement

Mental Toughness Questionnaire of Clough & et al

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: Compassion focused therapy Protocol (Gilbert, 2014) was performed through 8 90-minute Session, one session a week. Intervention was performed in a group.

#### Category

Behavior

### 2

#### Description

Intervention group 2: The Unified Protocol for Transdiagnostic Treatment (Barlow, 2011) was performed through 8 90-minute Session, one session a week. Intervention was performed in a group.

#### Category

Behavior

### 3

#### Description

Control group: Only taking medication was prescribed by a neurologist.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahin Shahr Oil Industry Clinic

##### Full name of responsible person

Dr. Ahmad Khatibi

##### Street address

Oil Industry Clinic, Imam Khomeini Street

##### City

Shahin Shahr

##### Province

Isfahan

##### Postal code

۸۳۱۶۶۳۳۱۱

##### Phone

+98 31 4522 9841

##### Email

m\_eshharian@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Rashid Riahy

##### Street address

Shahrekord Branch, Islamic Azad University, Rahmateyeh Blvd

##### City

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##### Province

Chahar-Mahal-va-Bakhtiari

##### Postal code

8813733395

##### Phone

+98 38 3336 1087

##### Email

riahi.r@iaushk.ac.ir

##### Web page address

http://research.iaushk.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Islamic Azad University

#### Proportion provided by this source

100

#### Public or private sector

Private

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Mehdi Ashharian

##### Position

Ph.D student

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Psychology

##### Street address

Shahrekord Branch, Islamic Azad University, Rahmateyeh Blvd

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

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**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

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**Email**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

-

**When the data will become available and for how long**

-

**To whom data/document is available**

-

**Under which criteria data/document could be used**

-

**From where data/document is obtainable**

-

**What processes are involved for a request to access data/document**

-

**Comments**

-